

The withdrawal of the rejection under 35 U.S.C. § 112, 2nd paragraph, is noted with appreciation.

The withdrawal of the rejection under 35 U.S.C. § 112, 1st paragraph, enablement, is noted with appreciation.

The withdrawal of the rejection under 35 U.S.C. § 102(b), is noted with appreciation.

2.. Claim Rejections

The rejection of claims 1, 3, 4 and 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is traversed.

Amended claim 1 now recites:

“A therapeutically effective composition comprising: an isolated and purified antibody (Jianye-2), which is specifically made against the synthetic amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) of the α -subunit of the (Na⁺+K⁺)-ATPase enzyme and its isoforms thereof, wherein the binding of the Jianye-2 antibody to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) in a therapeutic amount, increases myocyte intracellular diastolic or systolic calcium, without inhibiting (Na⁺+K⁺)-ATPase enzyme activity.”
(underscoring added for emphases)

Amended claim 1 avoids the rejection under 35 U.S.C. 112, first paragraph, by now reciting that “ ... the binding of the Jianye-2 antibody ... increases myocyte intracellular diastolic or systolic calcium, without inhibiting (Na⁺+K⁺)-ATPase enzyme activity.” Support can be found in Applicant’s PreGrant Publication, Paragraphs. [0079] and [0158]. Claims 3, 4 and 7 depend from claim 1 and are also considered to be in condition for allowance.

3.. Claim Rejections

The rejection of claims 1, 3, 4 and 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is traversed.

The Examiner states that it is unclear from the disclosure of the specification if “Jianye-2 “is a name given to any antibody, be it polyclonal, monoclonal or humanized that “...is specifically made against the synthetic amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) ... as is recited in claim 1 OR if “Jianye-2” is a name given to BOTH any antibody be it polyclonal, monoclonal or humanizer etc. and a particular monoclonal antibody having particular variable and constant domain sequences.

As recited in the PreGrant Publication, Par. [0089] “In accordance with the invention, it is preferred that the antibodies specifically bind to peptides having an amino acid sequence RSATEEEPPNDD (the antibody is referred to

herein as the "Jianye-2" antibody)". Thus, Jianye-2 is the name that is given to the very specific antibody which is specifically and clearly identified in claim 1 as being "made against the synthetic amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1)".

Thus, "Jianye-2" is a name given to an antibody that is specifically made against the synthetic amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1)..

In the penultimate paragraph on page 4 of the Office action the Examiner asserts that the statement "The therapeutically effective composition of claim 1 wherein the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) is an antigen or a component of a vaccine, and the antibody is a polyclonal..." is not clear. This is traversed.

As stated in the PreGrant Pub. Par [0039] Jianye-2 is an antibody and a vaccine. Claim 4 is amended to avoid the ambiguity issue raised by the Examiner and is now believed to be in condition for allowance.

Claim 7 is amended to depend from claim 1 and to more positively define the inventive departure. It is believed that claim 7 is now in condition for allowance.

4. Claim Rejections

The rejection of claims 1, 3, 4 and 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is traversed.

The Examiner's assertion that "Neither the instant record nor the prior art indicate that the "Jianye-2" antibody was known and readily available to the public, and the antibody is not obtainable by a repeatable method set forth in the specification" is not accurate. As is noted above in Section 3, in the PreGrant Publication, Par. [0089] it is clearly stated that "In accordance with the invention, it is preferred that the antibodies specifically bind to peptides having an amino acid sequence RSATEEEPPNDD (the antibody is referred to herein as the "Jianye-2" antibody)" (underscoring added for emphasis). Thus, Jianye-2 is the name that is given to the specific antibody which is clearly identified as being made against the synthetic amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which specifically binds to the amino acid sequence, RSATEEEPPNDD (SEO ID NO: 1) and which is obtainable by a repeatable method which is set forth in the specification. In this regard the Examiner's attention is directed to Applicant's PreGrant Publication, Paragraph Nos.; [0087 – 0090], [0097], [0120], [0122], [0142] and [0144]. :

Thus, contrary to the Examiners assertion, "Jianye-2" is obtainable by a repeatable method that is set forth in the specification.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully Submitted,

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